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EXAMINER	
PHONGSVIRATI, POONSIW	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,872	Applicant(s) ALSAFADI ET AL.
	Examiner SIND PHONGSVIRAJATI	Art Unit 3686

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-27 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08) _____
 Paper No(s)/Mail Date 20050607
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claim Objections

1. Claims 4-8, 14, 17-21 are objected to because said claims contain pseudo-acronyms not previously defined anywhere within the original disclosure: for example, claims 8 and 21 uses the pseudo-acronym, "GLIF" and "EON", the Applicant is advised to avoid using acronyms since said pseudo-acronym may be linked to a different definition term with the same initials. At the very least, Applicant should provide the proper antecedent basis for all pseudo-acronyms. Appropriate correction is required.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-27 are rejected under 35 U.S.C. 101 as being directed towards non-statutory subject matter.

3. As to claims 1-14, this claim recites a "system" comprising a first knowledge base, a second knowledge base, A third knowledge base, a domain ontology, a system configuration database, a system characteristics database, and an interference engine.

In applying the broadest and most reasonable interpretation in light of the specification and the level of ordinary skill in the art, Examiner interprets these limitations to envelop software per se embodiments.

Claims 1-14 rejected are under 35 U.S.C. 101 because data structures not claimed as embodied in computer-readable media are descriptive material per se and are not statutory because they are not capable of causing functional change in the computer. See, e.g., Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory). Such claimed data structures do not define any structural and functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a data structure defines structural and functional interrelationships between the data structure and the computer software and hardware components which permit the data structure's functionality to be realized, and is thus statutory.

4. Claims 15-27 are rejected under 35 U.S.C. 101 as being directed towards non-statutory subject matter based on Supreme Court precedent, and recent Federal Circuit decisions, *In re Bilski U.S. Court of Appeals Federal Circuit 88 USPQ2d 1385*. The machine-or-transformation test is a two-branched inquiry; an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article. See Benson, 409 U.S. at 70. Certain considerations are applicable to analysis under either branch. First, as illustrated by Benson and discussed below, the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility. See Benson, 409 U.S. at 71-72. Second, the involvement of the

machine or transformation in the claimed process must not merely be insignificant extra-solution activity. See *Flook*, 437 U.S. at 590.

5. The methods recited in claims 15-27 are not tied to a machine nor transform the underlying subject matter to a different state or thing. See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); and *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972).

6. Based on Supreme Court precedent, a method/process claim must (1) be tied to another statutory class of invention (such as a particular apparatus) (see at least *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing (see at least *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972)).

7. A method/process claim that fails to meet one of the above requirements is not in compliance with the statutory requirements of 35 U.S.C. 101 for patent eligible subject matter. Here claims 15-27 fail to meet the above requirements because they are not tied to another statutory class of invention.

8. Nominal recitations of structure in an otherwise ineligible method fail to make the method a statutory process. See *Benson*, 409 U.S. at 71-72. As Comiskey recognized, "the mere use of the machine to collect data necessary for application of the mental process may not make the claim patentable subject matter." *Comiskey*, 499 F.3d at

1380 (citing *In re Grams*, 888 F.2d 835, 839-40 (Fed. Cir.1989)). Incidental physical limitations, such as data gathering, field of use limitations, and post-solution activity are not enough to convert an abstract idea into a statutory process. In other words, nominal or token recitations of structure in a method claim do not convert an otherwise ineligible claim into an eligible one.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-3, 5, 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Born et al. (US 5,349,625) in view of Engleson et al. (US 5,781,442).

11. As to **Claims 1, 9-12**, Born teaches a system for guiding the selection of a value for each of a plurality of parameters needed to perform a procedure with a medical system (Abstract), comprising: a second knowledge base comprising patient information and therapy history (col. 2 line 64 to col. 3 line 22); a third knowledge base comprising clinical guidelines (col. 3 Lines 44-55); a domain ontology provides the semantic mapping between information in the first, second, and third knowledge bases; a system configuration database containing physical characteristics pertaining to the medical system (col. 3 lines 58-61, col. 5 lines 7-18); a system characteristics database containing mathematical formulas and algorithms for calibrating the medical system

based on the data in the system configuration database (Abstract, col. 1 line 64 to col. 2 line 2); and an interference engine for generating a set of parameters based on the information in the second and third knowledge bases, the system configuration database, and the system characteristics database (Abstract, Fig. 4-5, col. 3 lines 1-14). But Born does not specifically disclose a first knowledge base comprising procedures and treatment regimes and the interference engine generating a set of parameters including information from the first knowledge base. Engleson does teach of using a first knowledge base comprising procedures and treatment regimes and the interference engine generating a set of parameters including information from the first knowledge base (col. 9 lines 27-46). It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a first knowledge base containing procedures and treatment regimes and generating a set of parameters including information from the first knowledge base for the motivation for calculating the exact infusion required to give to the patient for medical imaging (Born, col. 3 lines 58-61).

12. As to **Claim 2**, Born teaches the system of claim 1 wherein said medical system is a medical imaging system (Abstract).

13. As to **Claim 3**, Born teaches the system of claim 2 wherein said medical imaging system is selected from the group consisting of computed tomography (CT) systems, x-ray systems (Abstract), magnetic resonance (MR) systems, positron emission tomography (PET) systems, ultrasound systems, and nuclear medicine systems.

14. As to **Claim 5**, Born does not specifically disclose the system of claim 2 wherein said patient information and therapy history is transmitted in conformance with a HL7 standard. Engleson does teach wherein said patient information and therapy history is transmitted in conformance with a HL7 standard (col. 11 lines 62-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to have patient information and therapy history transmitted in conformance with a HL7 standard for the motivation for conforming to a standard method of interfacing with a health care system.

15. Claims 4, 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Born et al. (US 5,349,625) in view of Engleson et al. (US 5,781,442) in further view of Matichuk (US 6,287,257).

16. As to **Claims 4, 6-7**, the combination of Born and Engleson does not specifically disclose the system of claim 2 wherein said patient information and therapy history is stored in conformance with a DICOM Standard; wherein said procedures and treatment regimes are stored in conformance with a DICOM standard; and wherein said DICOM standard is a DICOM Request Procedures Service Call. Matichuk does teach that the DICOM Modality Worklist is a structure to present information related to a particular set of tasks and specifies particular details for each task. For example, a worklist can present information about scheduled imaging procedure to an ultrasound system. HL7 is oriented towards the clinical and administrative aspects of a medical enterprise and allows disparate systems to intercommunicate freely. HL7 can communicate patient

information comprising, for example, patient medical history and demographics, encounter and visit histories, admit/discharge/transfer and patient tracking information, scheduling and referrals, orders and results (measurements, observations, impressions, reports), pharmacy and diet information, and census information (col. 5 lines 53-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to have patient information and therapy history stored in conformance with a DICOM Standard for the motivation for conforming to a standard method of interfacing with a health care system.

17. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Born et al. (US 5,349,625) in view of Engleson et al. (US 5,781,442) in further view of the Silvia Miksch ("Plan Management in the Medical Domain").

18. As to **Claim 8**, the combination of Born and Engleson does not specifically disclose the system of claim 2 wherein said clinical guidelines are represented in conformance with a standard selected from the group consisting of GLIF, EON, Asbru, Prodigy, Prestige, and ProForma. Miksch does teach wherein said clinical guidelines are represented in conformance with a standard selected from the group consisting of GLIF (page. 16, see section, "comparison"), EON, Asbru, Prodigy (page 6, see section, "Strategies and Planning"), Prestige, and ProForma. It would have been obvious to one of ordinary skill in the art at the time of the invention to have conformed with a standard

for clinical guidelines for the motivation for planning medical guidelines in a real-world domain (Miksich, pg. 1, see section, "Motivation and Introduction").

19. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Born et al. (US 5,349,625) in view of Engleson et al. (US 5,781,442) in further view of official notice.

20. As to **Claim 13**, the combination of Born and Engleson does not specifically disclose the system of claim 12 wherein said wide area network is the Internet. However, the Examiner takes official notice that a wide area network being described as the internet is well known in any art. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the internet for a wide area network for the motivation for remotely connecting different devices.

21. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Born et al. (US 5,349,625) in view of Engleson et al. (US 5,781,442) in further view of Lewis et al.(US 2001/0041992).

22. As to **Claim 14**, the combination of Born and Engleson does not specifically disclose the system of claim 2 wherein said domain ontology is a nomenclature in conformance with SNOMED RT/CT. Lewis does teach wherein said domain ontology is a nomenclature in conformance with SNOMED RT/CT (paragraph 49). It would have been obvious to one of ordinary skill in the art at the time of the invention to have a

nomenclature in conformance with SNOMED in a domain ontology for the motivation for using healthcare industry-accepted codes (paragraph 49).

23. As to **Claims 15-27**, claims 15-27 substantially recite similar limitations to claims 1-14 and are rejected using the same rationale and reasoning.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SIND PHONGSVIRAJATI whose telephone number is (571) 270-5398. The examiner can normally be reached on Monday - Thursday 8:00am-5:00pm (ET).

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. P./
Examiner, Art Unit 3686
31 July 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686